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REPLY UNDER
37 C.F.R. § 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 1617

PATENT
2801-0165P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Russell M. HAGEN et al. Conf.: 4024
Appl. No.: 09/985,679 Group: 1617
Filed: November 5, 2001 Examiner: R. S. TRAVERS
For: NOVEL MEDICAL USE FOR TACHYKININ ANTAGONISTS

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97(i)

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

August 13, 2004

Sir:

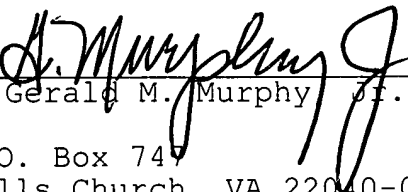
Applicants request that the attached references be placed in the record of the above-captioned application, under the provisions of 37 C.F.R. § 1.97(i). The relevancy of many of these documents will be discussed in the Appeal Brief, which will be filed in the near future. One document (the "Introduction to Pharmacology" reference) was cited in an opposition in the European Patent Office. Copies of two Office Actions from the related European Applications are also enclosed.

If the Examiner has any questions concerning this IDS, he is requested to contact the undersigned. If the Examiner wants to officially make these references of record, a PTO-1449 listing these references is attached for the Examiner's convenience. Alternatively, the Examiner may choose to list these references on a PTO-892.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

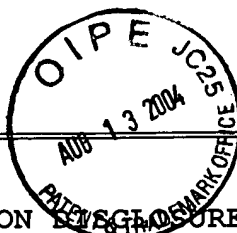
Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
Gerald M. Murphy Jr., #28,977
P.O. Box 747
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(703) 205-8000

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2801-0165P

Attachments:
PTO-1449
Documents



Form PTO-1449

**INFORMATION CONCERNING CITATION
IN AN APPLICATION**

(Use several sheets if necessary)

ATTY. DOCKET NO.
2801-0165PAPPLICATION NO.
09/985,679APPLICANT
Russell M. HAGAN et al.FILING DATE
November 5, 2001GROUP
1617**U. S. PATENT DOCUMENTS**

| EXAMINER INITIAL | DOCUMENT NUMBER | Kind | DATE | NAME | CLASS | SUB CLASS | FILING DATE IF APPROPRIATE |
|---------------------|-----------------|------|------------|----------------|-------|--------------|-------------------------------|
| | US 5,719,147 | A | 1998-02-17 | Dorn et al. | | | |
| | US 6,048,859 | A | 2000-04-11 | Dorn et al. | | | |
| | US 6,096,742 | A | 2000-08-01 | Crocker et al. | | | |
| | US 6,235,735 | B1 | 2001-05-22 | Dorn et al. | | | |
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FOREIGN PATENT DOCUMENTS

| Office | DOCUMENT NUMBER | Kind | DATE | COUNTRY | CLASS | SUB CLASS | TRANSLATION | |
|--------|--------------------|------|------|---------|-------|--------------|-------------|----|
| | | | | | | | YES | NO |
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OTHER DOCUMENTS

(Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)

Ctr. for Drug Evaluation and Research, Food and Drug Admin., Electronic Orange Book (24th ed. Cum. Supp. 6 June 2004) at <http://www.fda.gov/cder/ob/>, query "Alosetron". Patent data last updated August 11, 2004.

Physicians' Desk Reference, PDR® Electronic Library™, PDR Entry for EMEMD® (Aprepitant), printed from website on August 11, 2004.

Ctr. for Drug Evaluation and Research, Food and Drug Admin., Electronic Orange Book (24th ed. Cum. Supp. 6 June 2004) at <http://www.fda.gov/cder/ob/>, query "Aprepitant". Patent data last updated August 5, 2004.

Physicians' Desk Reference, PDR® Electronic Library™, PDR Entry for ANZEMET® (Dolasetron), printed from website on August 11, 2004.

Ctr. for Drug Evaluation and Research, Food and Drug Admin., Electronic Orange Book (24th ed. Cum. Supp. 6 June 2004) at <http://www.fda.gov/cder/ob/>, query "Dolasetron". Patent data last updated August 11, 2004.

Physicians' Desk Reference, PDR® Electronic Library™, PDR Entry for KYTRIL® (Granisetron), printed from website on August 11, 2004.

Ctr. for Drug Evaluation and Research, Food and Drug Admin., Electronic Orange Book (24th ed. Cum. Supp. 6 June 2004) at <http://www.fda.gov/cder/ob/>, query "Granisetron". Patent data last updated August 11, 2004.

Physicians' Desk Reference, Vol. 46, 1069-71 (1992), Ondansetron (brand name ZOFRAN®)

Ctr. for Drug Evaluation and Research, Food and Drug Admin., Electronic Orange Book (24th ed. Cum. Supp. 6 June 2004) at <http://www.fda.gov/cder/ob/>, query "Ondansetron". Patent data last updated August 5, 2004.

Physicians' Desk Reference, PDR® Electronic Library™, PDR Entry for ALOXI® (Palonosetron), printed from website on August 11, 2004.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary) | ATTY. DOCKET NO. 2801-0165P | APPLICATION NO. 09/985,679 |
| | APPLICANT Russell M. HAGAN et al. | |
| | FILING DATE November 5, 2001 | GROUP 1617 |

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| | US | | | | | | |
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OTHER DOCUMENTS (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)

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|--|---|
| | Ctr. for Drug Evaluation and Research, Food and Drug Admin., <u>Electronic Orange Book</u> (24 th ed. Cum. Supp. 6 June 2004) at http://www.fda.gov/cder/ob/ , query "Palonosetron". Patent data last updated August 11, 2004. |
| | Office Action issued by the European Patent Office on October 27, 2003, in corresponding European Application No. 99 200 338.4 - 2107 |
| | Office Action issued by the European Patent Office on October 27, 2003, in corresponding European Application No. 99 200 337.6 - 2107 |
| | <u>Introduction to Pharamcology</u> , New Edition, 1981, Nanzandoh Co., Ltd.:Tokyo, Japan, p. 7 |
| | <u>Merck Index</u> , 11 th ed. (1989) p. 6802, Ondansetron |
| | Seyfried C.A. et al., <u>Drug Metabolism and Drug Interactions</u> , Vol. 9, No. 2, pp. 149-160, 1991 |
| | L. Grélot et al., <u>British Journal of Pharmacology</u> (1998) 124, 1643-1650 |
| | Watson et al., <u>British Journal of Pharmacology</u> 115, 84-94 (1995) |
| | Gonsalves et al., <u>European Journal of Pharmacology</u> 305, 181-185 (1996) |
| | Gardner et al., <u>Regulatory Peptides</u> 65, 45-53 (1996) |
| | Singh et al., <u>European Journal of Pharmacology</u> 321, 209-216 (1997) |
| | Rupniak et al., <u>European Journal of Pharmacology</u> 326, 201-209 (1997) |

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OTHER DOCUMENTS (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)Gardner et al., Neuropharmacology 37, 1643-1644 (1998)Tattersall et al., Neuropharmacology 39, 652-663 (2000)Tsuchiya et al., Pharmacology 66, 144-152 (2002)

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